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Declaration under Rule 4.17:

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(54) Title: **NEUROSTIMULATION LEAD STYLET HANDLE**

(57) Abstract: An implantable neurological stimulation lead with improved stylet handle comprises a lead body, at least one conductor, at least one electrical contact, at least one electrode, a stylet wire, and a stylet handle. The lead body has a body proximal end, a body distal end, and a stylet lumen. The conductor is contained in the lead and extends from the body proximal end to the body distal end, and the conductor is electrically insulated. The electrical connector is carried on the body proximal end and electrically connected to the conductor. The electrode is carried on the body distal end and electrically connected to the conductor. The stylet wire is configured for insertion into the stylet lumen to stiffen the lead body. The stylet handle is selectively coupled to the stylet wire. The stylet handle has a lead carrier and at least one gripper carried in the lead carrier configured to grip the lead body at a selected point along the lead body or lead proximal end.

NEUROSTIMULATION LEAD STYLET HANDLE

FIELD OF THE INVENTION

5 This disclosure relates to a medical device and more particularly to implantable neurological electrical stimulators and implantable electrical stimulation leads.

BACKGROUND OF THE INVENTION

 The medical device industry produces a wide variety of electronic and mechanical devices for treating patient medical conditions such as pacemakers, defibrillators, neuro-stimulators and
10 therapeutic substance delivery pumps. Medical devices can be configured to be surgically implanted or connected externally to the patient receiving treatment. Clinicians use medical devices alone or in combination with therapeutic substance therapies and surgery to treat patient medical conditions. For some medical conditions, medical devices provide the best and sometimes the only therapy to restore an individual to a more healthful condition and a fuller life.
15 One type of medical device is an implantable neurological stimulation system that can be used to treat conditions such as pain, movement disorders, pelvic floor disorders, gastroparesis, and a wide variety of other medical conditions. The neurostimulation system typically includes a neurostimulator, a stimulation lead, and an extension such as shown in Medtronic, Inc. brochure "Implantable Neurostimulation System" (1998). More specifically, the neurostimulator system
20 can be an Itrel II® Model 7424 or an Itrel 3® Model 7425 available from Medtronic, Inc. in Minneapolis, Minnesota that can be used to treat conditions such as pain, movement disorders and pelvic floor disorders. The neurostimulator is typically connected to a stimulation lead that has one or more electrodes to deliver electrical stimulation to a specific location in the patient's body.

 The lead and stylet combination are part of the implantable neurostimulation system. The
25 neuro stimulation lead is placed in the desired location of the body. The stylet wire and handle combination are used to give the lead stiffness during implantation and to aid in maneuvering the lead into the desired position. Currently several types of lead and stylet combinations exist for this purpose. An example of a stylet that engages the proximal end of the lead connector region in

specified locations is the Pisces Quad Lead Model 3487A stylet available from Medtronic, Inc., Minneapolis, Minnesota, USA.. The location of the distal end of the stylet can potentially reside in different locations in the electrode region due to tolerances in both the lead and the stylet.

Another combination offers a stylet that terminates at a definite point in the distal end of the lead and a handle that engages the lead at specific points at the lead proximal end. For this stylet lead combination each stylet must be custom made to fit each lead. All custom fit stylets are packaged in the lead kit. If a physician requires the use of a different stylet, a stylet from another kit will not work as intended. A third type of lead stylet system exists where the stylet terminates at a specific point in the distal end of the lead, but does not engage the lead at the proximal end. This makes maneuvering the lead more difficult. Another example of a stylet handle is shown in U.S. Patent No. 6,203,506 "Operating Device For A Stylet Unit" by Boström (March 20, 2001).

Thus, embodiments of the implantable neurological stimulation lead with improved stylet handle are disclosed that improve physician placement control and reduce manufacturing cost.

BRIEF SUMMARY OF THE INVENTION

An implantable neurological stimulation lead with improved stylet handle comprises a lead body, at least one conductor, at least one electrical contact, at least one electrode, a stylet wire, and a stylet handle. The lead body has a body proximal end, a body distal end, and a stylet lumen. The conductor is contained in the lead and extends from the body proximal end to the body distal end, and the conductor is electrically insulated. The electrical connector is carried on the body proximal end and electrically connected to the conductor. The electrode is carried on the body distal end and electrically connected to the conductor. The stylet wire is configured for insertion into the stylet lumen to stiffen the lead body. The stylet handle is selectively coupled to the stylet wire. The stylet handle has a lead carrier and at least one gripper carried in the lead carrier configured to grip the lead body at a selected point along the lead body or lead proximal end. Many embodiments and methods of operation of the implantable neurological stimulation lead with improved stylet handle are possible.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a general environmental view for a neurostimulation system embodiment;

FIG. 2 shows a neurostimulation system embodiment;

FIG. 3 shows a neurostimulation lead embodiment;

5 FIG. 4 shows another neurostimulation lead embodiment;

FIG. 5 shows a stimulation lead and stylet handle embodiment;

FIG. 6 shows a stimulation lead and another stylet handle embodiment;

FIG. 7 shows a cross section of stimulation lead distal end with a stylet stop embodiment;

FIG. 8 shows an enlarged drawing of a gripper embodiment;

10 FIG. 9 shows a stylet wire being retained in a stylet handle embodiment;

FIG. 10 shows a stylet wire decoupled from a stylet handle embodiment;

FIG. 11 shows a stimulation lead being gripped by a stylet handle embodiment; and,

FIG. 12 shows a flow diagram of a method for inserting a stylet in a stimulation lead embodiment.

DETAILED DESCRIPTION OF THE INVENTION

15 FIG. 1 shows a general environmental view 10 for an implantable neurostimulation system embodiment. Neurostimulation systems are used to treat conditions such as pain, movement disorders, pelvic floor disorders, gastroparesis, and a wide variety of other medical conditions. The neurostimulation system 20 includes a neurostimulator 22 such as an Itrel II® Model 7424 or
20 an Itrel 3® Model 7425 available from Medtronic, Inc. in Minneapolis, Minnesota, a stimulation lead extension 30, and a stimulation lead 40. The neurostimulator 22 is typically implanted subcutaneously in the patient's body 28 at a location selected by the clinician. The stimulation lead 40 is typically fixed in place near the location selected by the clinician using a device such as the adjustable anchor.

FIG. 2 shows an implantable neurostimulation system 20 comprising an implantable neurostimulator 22, a stimulation lead 40, and a lead extension 30. The implantable neurostimulator 22 has a housing, a power supply carried in the housing, and stimulation electronics coupled to the battery and coupled to a connector block 26, which is also known as a terminal block. The implantable neurological stimulator 22 can be a Medtronic Itrel II® Model 7424 or an Itrel 3® Model 7425 or the like, both of which are commercially available. The neurological monitor can be a Medtronic Neurodiagnostics Keypoint monitoring system.

FIG. 3 shows a percutaneous neurological stimulation lead and FIG. 4 shows a surgical paddle stimulation lead. The neurological lead 40 can be configured as a neurological stimulation lead, a neurological sensing lead, and a combination of both as a neurological stimulation and sensing lead. The implantable neurological stimulation lead 40 with improved stylet handle 52 comprises a lead body 43, at least one conductor 44, at least one electrical connector 46, at least one electrode 42, and a stylet 50. The lead body 43 has a body proximal end 45, a body distal end 41, and a stylet lumen 48. The lead body 43 can be composed of a wide variety of materials and configurations. Materials can include, but not be limited to silicone rubber, polyurethane, fluoropolymers and the like. Configurations could include monolumen and multilumen tubings. The lead body 43 can be configured with a stylet stop 49 in the lead distal end 41. The stylet stop 49 provides a place for the stylet wire 54 to contact before the lead body 43 is gripped. The stylet stop 49 controls where the stylet wire 54 terminates in the stimulation lead 40. With the use of a stylet stop 49 every stimulation lead 40 will have the stylet wire 54 terminate at the same position. This increases the consistency of maneuvering the stimulation lead 40 in the body 28 by a clinician.

The conductor 44, electrical connector 46 and electrode 42 provide an electrical path through the lead body 43. The conductor 44 is contained in the lead 40 extending from the body proximal end 45 to the body distal end 41. The conductor 44 can be manufactured from such as MP35N, silver drawn filled tubing (Ag-DFT), Platinum iridium alloys, platinum and the like. Conductor 44 configurations could include stranded, braided or solid wire configured in linear or helical coil arrangements. The conductor 44 is electrically insulated with a polymer. The polymer could be, but is not limited to, ethylene tetrafluoroethylene (ETFE), polytetrafluoroethylene (PTFE), silicone rubber or polyurethane. Other materials that act as

electrical insulators can be used. The electrical connector 46 is carried on the body proximal end 45 and electrically connected to the conductor 44. The electrical connector 46 is configured to couple to the implantable neurological stimulator 22 or neurological monitor. The electrode 42 is carried on the body distal end 41 and electrically connected to the conductor 44.

5 FIGS. 5-11 show various views and embodiments of the implantable neurological stimulation lead 40 with improved stylet handle 52. The stylet 50 includes a stylet wire 54 and a stylet handle 52 which may be selectively coupled. The stylet wire 54 is configured for insertion into the stylet lumen 48 to stiffen the lead body 43. Materials can include, but not be limited to Stainless Steel and Tungsten. The stylet wire 54 can vary in length and characteristics including
10 but not limited to straight, bent or curved tipped, as well as having a full radius tip or a ball tip. The stylet handle 52 may or may not be connected to the stylet wire 54. The stylet handle 52 has a lead carrier 56 and at least one gripper 58 carried in the lead carrier 56 configured to grip the lead body 43 at a selected but not specific point along the lead body 43 or lead proximal end 45. The selected point can be any point along the lead body 43 other than the lead body distal end 41.
15 The stylet handle 52 can also serve as a means for grasping the lead body 43 selectively connected to the stylet wire 54, the means for grasping configured to grip the lead body 43 at a selected point along the lead body 43 or lead proximal end 45. The lead carrier 56 is designed so a thumb or forefinger has room to push the stimulation lead 40 into the lead carrier 56. When the lead body 43 is engaged in the lead carrier 56 of the stylet handle 52 the stylet wire 54 remains in contact
20 with the stylet stop 49 in the stylet lumen 48 in the lead body distal end 41. The lead carrier 56 is designed to compensate for the tolerances in both the stimulation lead 40 and the stylet 50. When the stylet wire 54 is engaged in the stylet handle 52 at least one gripper 58 in the stylet carrier 56 must grip the stimulation lead 40. The stylet 50 does not have to be custom made in order to fit a specific stimulation lead 40. Any manufactured stimulation lead 40 will mate with any
25 manufactured stylet 50. Materials for the stylet handle 52 can include, but not be limited to polycarbonate, polypropylene, and polyetherimide.

Some embodiments of the stylet 50 can include a stylet release 60 in the stylet handle 52. The stylet release 60 has an engaged position where the stylet wire 54 is coupled to the stylet
30 handle 52 and a disengaged position where the stylet wire 54 is decoupled from the stylet handle 52. When the stylet release 60 is disengaged a lead opening 62 is created to permit the stylet

handle 52 to be moved toward the lead distal end 41 without being encumbered by the stylet wire 54. The lead proximal end 45 moves completely through the lead opening 62 in the stylet handle 52. This allows the stylet handle 52 to engage the stimulation lead 40 anywhere on the lead body 43 or lead proximal end 45. Engaging the stimulation lead 40 in the lead body 43 allows a
5 physician to torque and maneuver the stimulation lead 40. The stylet handle 52 can be moved from a more proximal position to a distal position on the lead 40 thus increasing the reactivity of the lead distal end 41. As the stimulation lead 40 is pushed into the body 28 the stylet handle 52 can be relocated proximally on the lead body 43.

FIG. 12 shows a flowchart of a method for inserting a stylet 50 in a neurological
10 stimulation lead 40. The method begins by aligning 64 a stylet wire 54 with a stylet lumen 48 of a lead body proximal end 45. Once aligned, the stylet wire 54 is inserted 66 into the stylet lumen 48. The stylet wire 54 is pushed 68 through the stylet lumen until the stylet wire 54 contacts a stylet stop 49 in the stylet lumen 48 of a lead body distal end 41. The stylet stop 49 controls where the stylet wire 54 terminates in the stimulation lead 40. With the use of a stylet stop 49
15 every stimulation lead 40 will have the stylet wire 54 terminate at the same position. This increases the consistency of maneuvering the stimulation lead 40 in the body 28 by a clinician. Once the stylet wire 54 is fully inserted, the lead body 43 is pressed 70 into the lead carrier 56 in the stylet handle 52 by pressing the lead body 43 into the lead carrier 56 using the thumb or forefinger. The lead carrier 56 is designed so a thumb or forefinger has room to push the
20 stimulation lead 40 into the lead carrier 56. By pushing the lead body 43 into the lead carrier 56 the lead body 43 is gripped with at least one gripper 58 in the lead carrier 56. The lead body 43 is typically but not exclusively gripped on the lead body proximal end 45. When the stylet wire 54 is engaged in the stylet handle 52 and the stylet wire contacts the stylet stop 49, at least one gripper 58 in the stylet carrier 56 will grip the stimulation lead 40. The stylet 50 does not have to
25 be custom made in order to fit a specific stimulation lead 40. Any manufactured stimulation lead 40 will mate with any manufactured stylet 50. This provides flexibility for clinicians implanting a neurostimulation system 20. During the implantation procedure many clinicians bend the stylet wire 54 to increase maneuvering of the stimulation lead 40. Once a stylet wire 54 is bent it cannot be easily returned to the original configuration. It is possible to use several stylets 50 during the
30 implantation procedure. The stylet 50 described in this document allows easy replacement of the any stylet 50 with a new stylet 50.

Thus, embodiments of the stimulation lead stylet handle are disclosed. One skilled in the art will appreciate that the present invention can be practiced with embodiments other than those disclosed. The disclosed embodiments are presented for purposes of illustration and not limitation, and the present invention is limited only by the claims that follow.

What is claimed is:

1. An implantable neurological stimulation lead with improved stylet handle, comprising:

5 a lead body having a body proximal end, a body distal end, and a stylet lumen;
 at least one conductor contained in the lead extending from the body proximal end
 to the body distal end, the conductor being electrically insulated;
 at least one electrical connector carried on the body proximal end and electrically
 connected to the conductor;
10 at least one electrode carried on the body distal end and electrically connected to
 the conductor;
 a stylet wire configured for insertion into the stylet lumen to stiffen the lead body;
 and,
 a stylet handle connected to the stylet wire, the stylet handle having a lead carrier
 and at least one gripper carried in the lead carrier configured to grip the lead body
15 at a selected point along the lead body or lead proximal end.

2. The implantable neurological stimulation lead as in claim 1, wherein the selected point is any point along the lead body other than the lead body distal end.

3. The implantable neurological stimulation lead as in claim 1, further comprising a stylet stop in the lead distal end for the stylet wire to contact before the lead body is gripped in the lead carrier.

4. The implantable neurological stimulation lead as in claim 1, further comprising
 a stylet release in the stylet handle, the stylet release having an engaged
 position where the stylet wire is coupled to the stylet handle and a y; and,
 a stylet handle connected to the stylet wire, the stylet handle having a lead carrier
25 and at least one gripper carried in the lead carrier configured to grip the lead body
 at a selected point along the lead body.

5. A method for inserting a stylet in a neurological stimulation lead, comprising:
 aligning a stylet wire with a stylet lumen of a lead body proximal end;
 inserting the stylet wire into the stylet lumen;
30 stopping insertion of the stylet wire when the stylet wire contacts a stylet stop in
 the stylet lumen of a lead body distal end;

inserting the lead body in a stylet handle lead carrier; and,

gripping the lead body with at least one gripper located in the stylet handle lead carrier while the stylet wire remains in contact with the stylet stop in the stylet lumen in the lead body distal end.

- 5 6. The method as in claim 5, wherein the gripping the lead body is performed on the lead body proximal end.

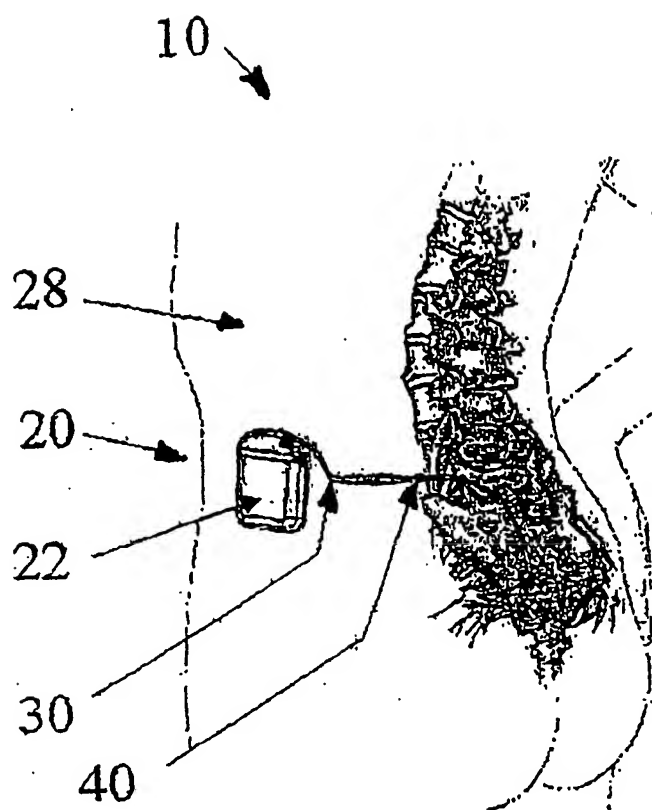
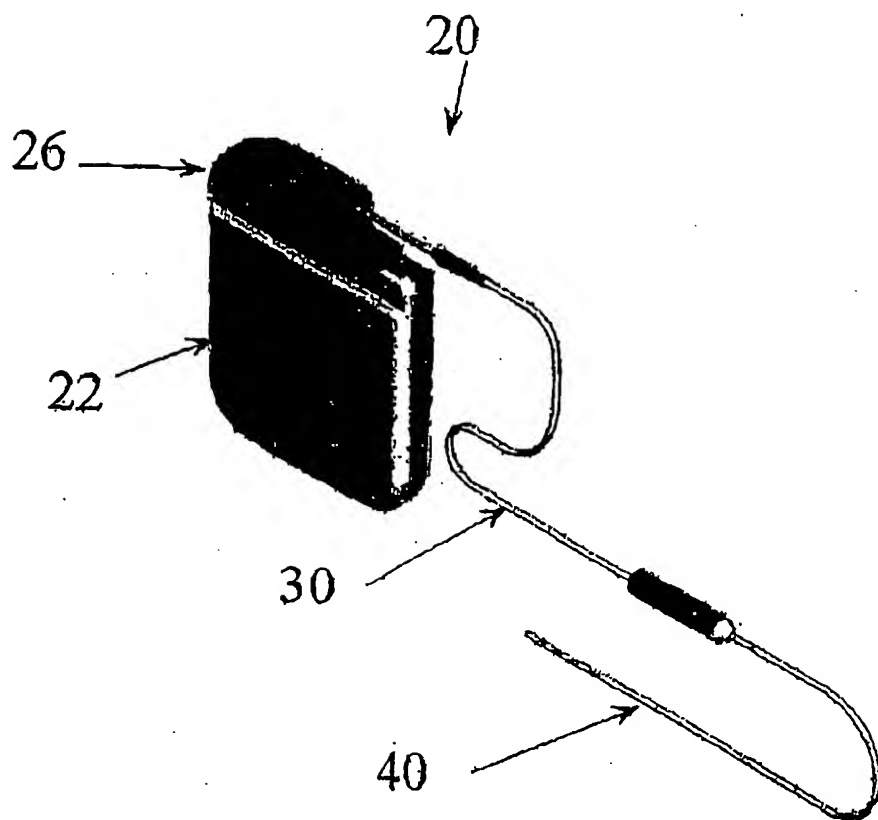
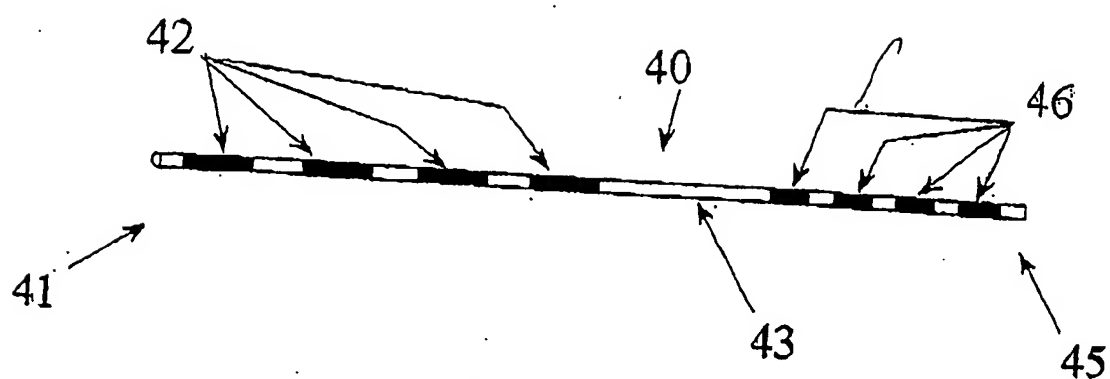
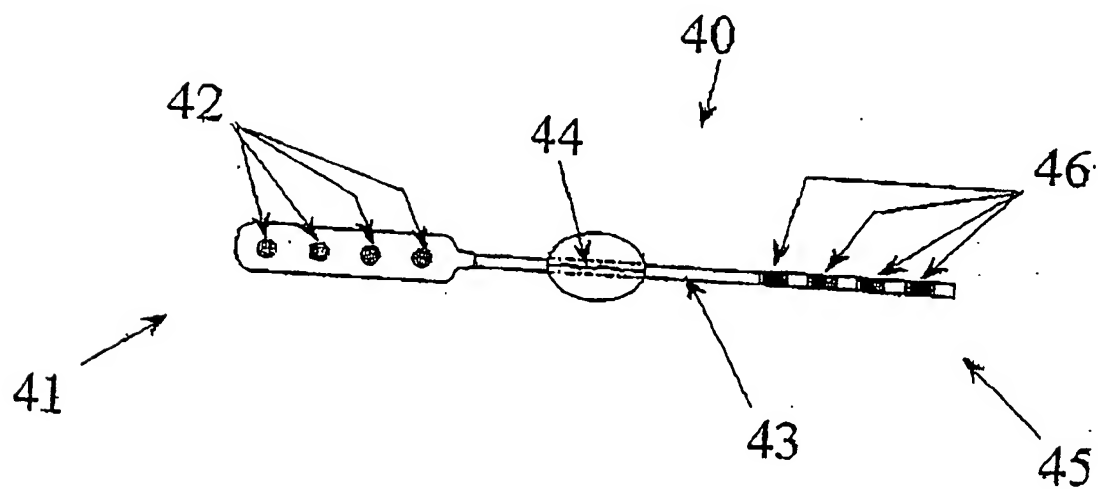
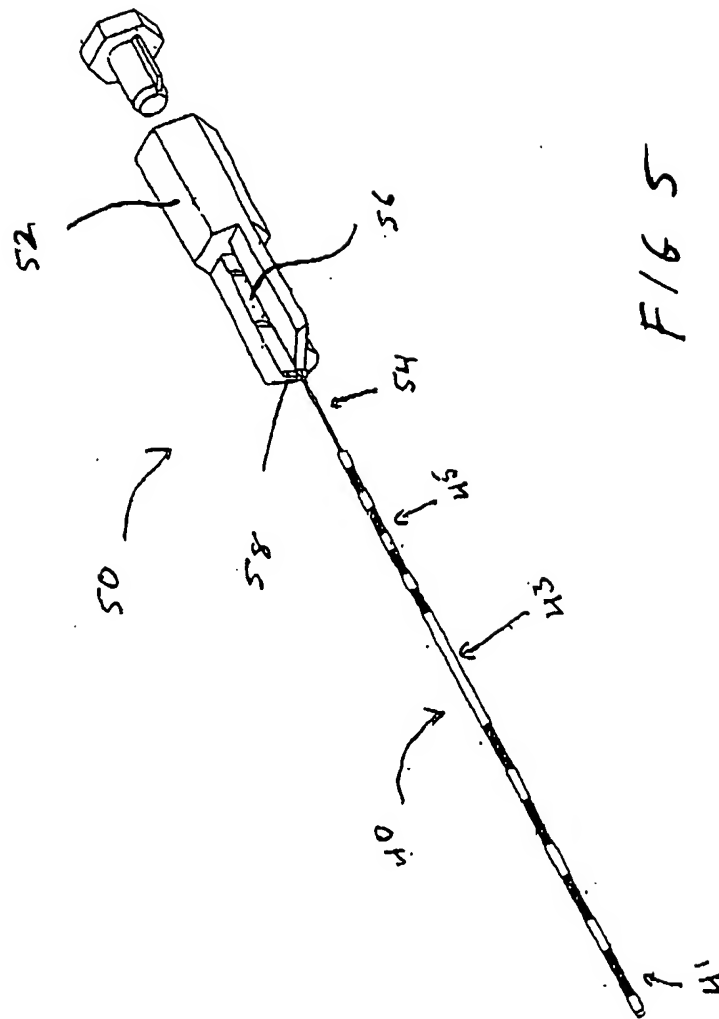
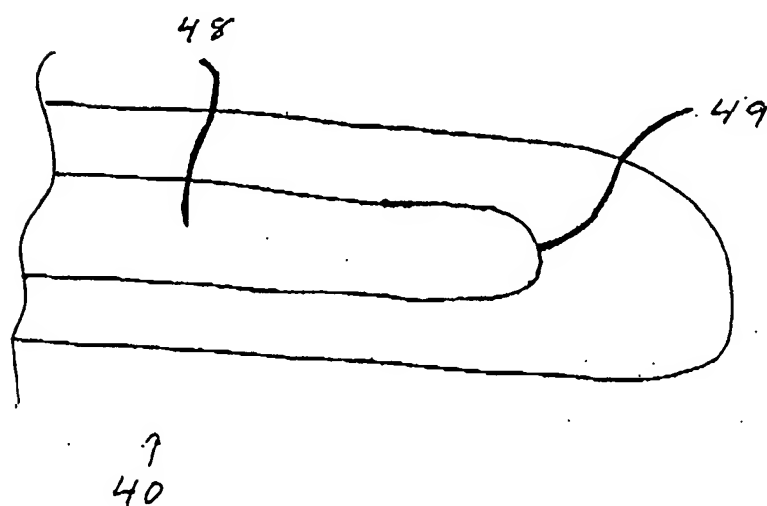
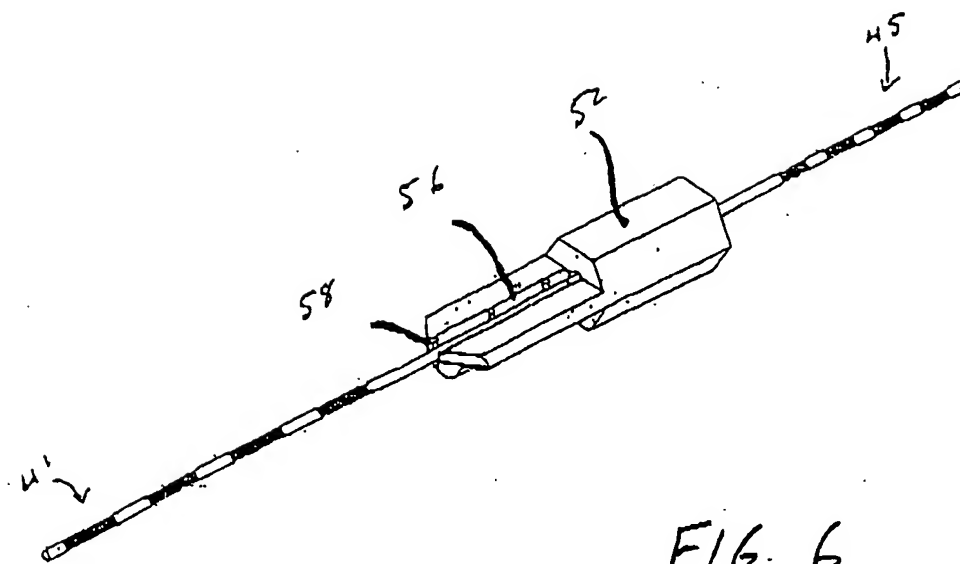


Fig. 1

*Fig. 2*

*Fig. 3**Fig. 4*





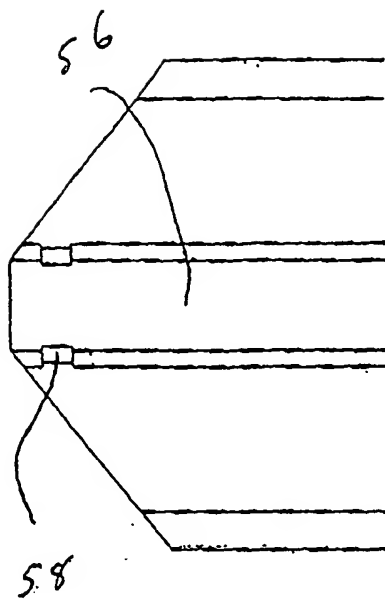


FIG. 8

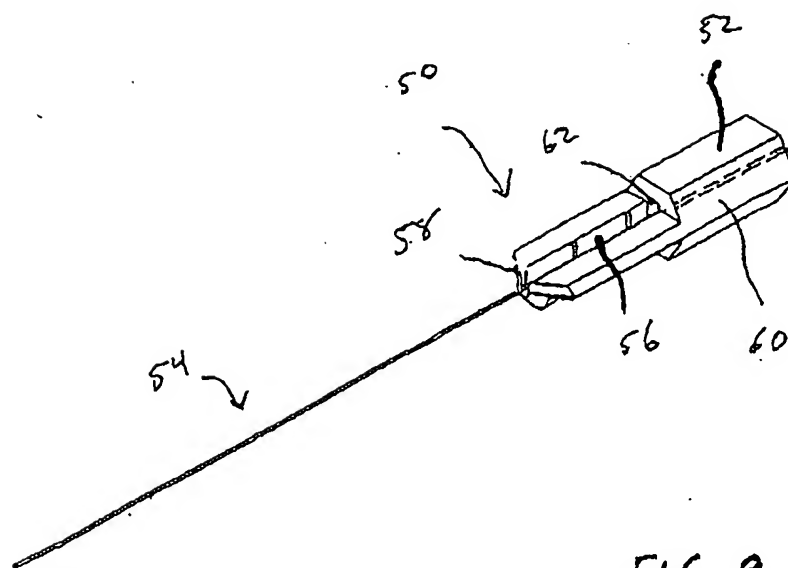


FIG. 9

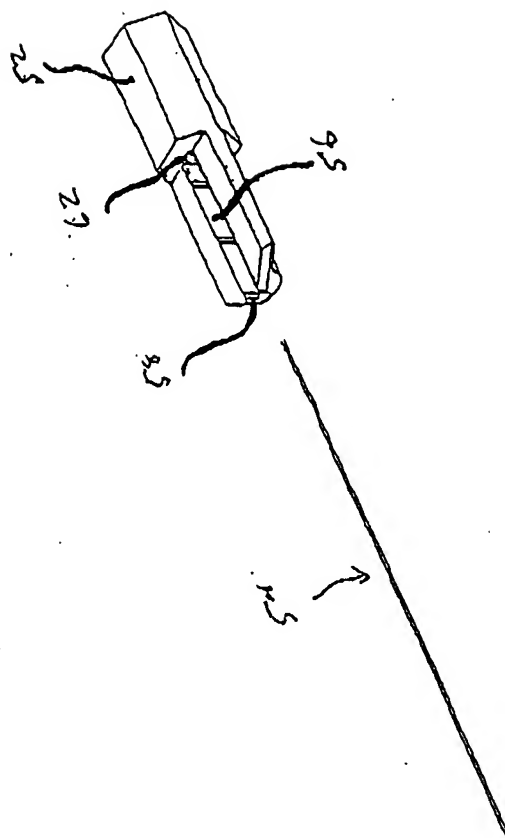
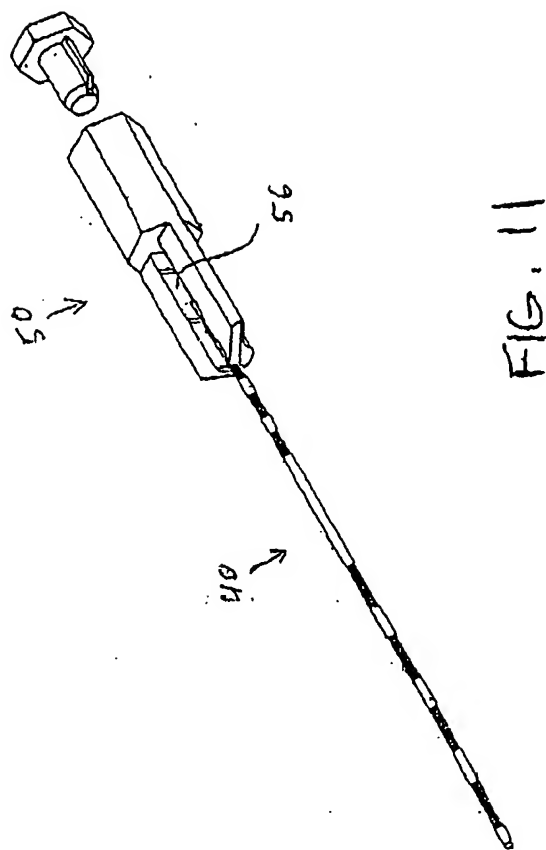


FIG. 10



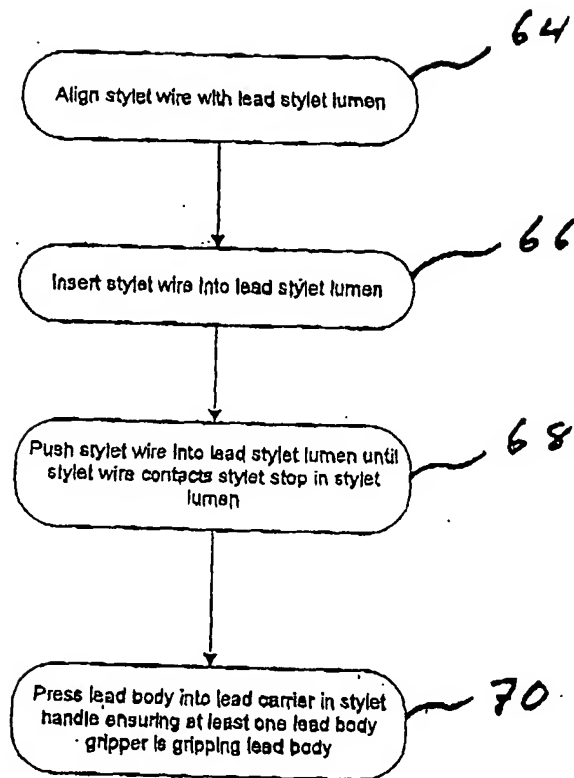


FIG. 12

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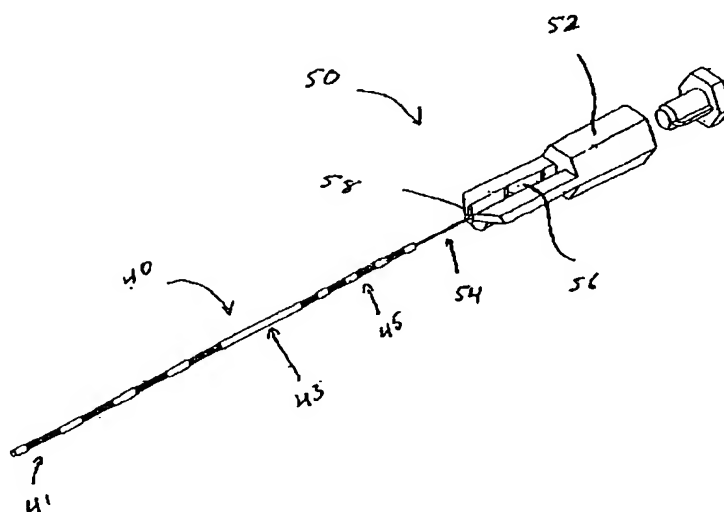
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KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
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SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ,

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VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

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IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01 21243 A (HILL ROLF ;JARL PER (SE); WARGELIUS MARIA (SE); JOHANSSON GOERAN ()) 29 March 2001 (2001-03-29) column 4, line 23 -column 5, line 23; figures 2-4	1-3,5,6
Y	column 4, line 6-21; figure 1	4
X	EP 0 450 181 A (SIEMENS AG ;SIEMENS ELEMA AB (SE)) 9 October 1991 (1991-10-09) column 3, line 25-37; figures 1-3	1,2
Y	column 4, line 36 -column 5, line 42; figure 4	4
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Date of the actual completion of the international search

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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